510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 11 2012

Weck® Reusable Obturator

A. Name, Address, Phone, and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-4918
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B. Contact Person

Holly Kornegay
Regulatory Affairs Associate

C. Date Prepared

June 14, 2012

D. Device Name

Trade Name:	Weck® Reusable Obturator
Common Name:	Surgical Trocar
Regulatory Classification:	Class II
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Regulation Name:	Arthroscope and Accessories
Product Code:	GCJ

E. Device Description

The Weck® Reusable Obturator is used to establish penetration into the abdominal cavity during laparoscopic surgical procedures. When used with the appropriate corresponding disposable cannula, the system creates a port of entry into the patient, facilitating the access of various diameter devices, while maintaining insufflation at the surgical site. The obturator is positioned into the peritoneum as a guide to the corresponding cannula during minimally invasive surgical procedures, and then is removed in order to provide a pathway for the insertion and removal of various sized surgical devices. The Weck® Reusable Obturator is intended to be used by trained physicians.

F. Indications for Use

The Weck Reusable Obturator is indicated for use with appropriate disposable Weck Vista cannulas in thoracic, abdominal, and gynecologic minimally invasive surgical procedures to provide a pathway for the introduction of endoscopic surgical devices.

G. Contraindications

Where minimally invasive techniques are contraindicated, other methods and instrumentation should be employed.

H. Substantial Equivalence

The proposed Weck® Reusable Obturator is substantially equivalent to the predicate disposable obturator used with the following devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
ADAPt™ Laparoscopic Port and Accessory	Teleflex Medical, Inc. / Taut, Inc.	K010007	02/22/01
ADAPt™ Universal Laparoscopic Port	Teleflex Medical, Inc.	K082156	09/10/2008

I. Comparison to Predicate Devices

This proposed product line extension to K010007, *ADAPt™ Laparoscopic Port and Accessory*, and K082156, *ADAPt™ Universal Laparoscopic Port*, affords a new product code for a reusable stainless steel obturator.

The incorporation of the stainless steel material will allow trained physicians the ability to reuse the obturator, without any modification to material or dimensions of the compatible systems noted above.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Weck® Reusable Obturator and the predicates has been performed. The results of this comparison demonstrate that the Weck® Reusable Obturator is compatible with the cannulas of the systems noted above and additionally offers the feature of "reusability".

L. Performance Data

The bench testing has been performed to verify that the performance of the proposed Weck® Resuable Obturator is substantially equivalent to the predicate obturators and that the Weck® Reusable Obturator is seamlessly interchangeable with the predicate obturator.

L. Conclusion

Based upon the comparative test results, the proposed Weck® Reusable Obturator is substantially equivalent in performance to the predicate devices cleared to market via 510(k) K010007 and K082156. The modifications made to the Weck® Reusable Obturator do not introduce any new issues of safety and effectiveness. IFU updates have been integrated according to ISO 17664:2004, Sterilization of Medical Devices, to ensure appropriate cleaning and sterilization instructions for reusable devices, by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Teleflex Medical, Incorporated
% Ms. Holly Kornegay
Regulatory Affairs Associate
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K121796
Trade/Device Name: Weck® Reusable Obturator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 1, 2012
Received: September 17, 2012

DEC – 4 2012

Dear Ms. Kornegay:

This letter corrects our substantially equivalent letter of October 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure: New Indication For Use

Indications for Use

510(k) Number: K121796

Device Name: Weck® Reusable Obturator

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121796